



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Claudio Soto-Jara

Serial No.: 10/726,366

Filed: December 3, 2003

For: PEPTIDE ANALOGS SUITABLE  
FOR IN VIVO USE IN THE TREATMENT  
OF DISEASES ASSOCIATED WITH  
ABNORMAL PROTEIN-FOLDING INTO  
AMYLOID, AMYLOID-LIKE DEPOSITS  
OR BETA-SHEET RICH PATHOLOGICAL  
PRECURSOR THEREOF

Confirmation No.: 8149

Examiner: To be assigned

Group Art Unit: 1647

Attorney Docket No.: 3154-6317.2US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 10, 2004  
Date

A Blackburn  
Signature

Aubry Blackburn  
Name (Type/Print)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

Pursuant to 37 C.F.R. § 1.98(d), a copy of any patent, publication or other information listed in the Information Disclosure Statement ~~is not required~~ to be provided if it was

The PTO did not receive the following  
listed items (s) FGN and NPLs

Serial No.: 10/726,366

previously cited by or submitted to the office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. § 120.

Accordingly, no copy of information marked with a pound sign (#) is enclosed because it was previously cited or submitted to the patent office in a prior application which is properly identified above, and is relied upon for an earlier filing date. The references are as follows:

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US - 5,780,587	7-1998	Potter et al.
#US - 5,817,626	10-1998	Findeis et al.
#US - 5,854,215	12-1998	Findeis et al.
US - 5,854,204	12-29-1998	Findeis et al.
#US - 5,948,763	9-1999	Soto-Jara et al.
#US - 5,985,242	11-1999	Findeis et al.
#US - 6,462,171 B1	10-2002	Soto-Jara et al.
US - 6,689,753 B1	2-10-2004	Claudio Soto-Jara

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO-97/21728	6-1997	KAROLINSKA INNOVATIONS AB

Other Documents

#ADESSI et al. Beta-Sheet Breaker Strategy for the Treatment of Alzheimer's Disease. Drug Development Res 56(2): 184-193, 2002.

#BLONDELLE et al. Polyalanine-based Peptides as Models for Self-Associated Beta-Pleated-Sheet Complexes. Biochemistry 36: 8393-8400, 1997.

European Search Report, EP 00 97 6928, dated September 10, 2004.

FAUCHERE et al., "Evaluation of the Stability of Peptides and Pseudopeptides as a Tool in Peptide Drug Design," *Advances in Drug Research*, 1992, pp. 127-159, vol. 23,

GANTE, Joachim, "Peptidomimetics--Tailored Enzyme Inhibitors," *Angewandte Chemie*, 16 September 1994, pp. 1699-1720, vol. 33, no. 17.

#GOLABEK et al. The Interaction Between Apolipoprotein E and Alzheimer's Amyloid Beta-Peptide is Dependent on Beta-Peptide Conformation. *J Biol Chem* 271(18): 10602-10606, 1996.

#HETENYI et al. Computational Studies on the Binding of the Beta-Sheet Breaker (BSB) Peptides on Amyloid BetaA(1-42). *J Molec Structure* 542: 25-31, 2001.

#PERMANNE et al. Reduction of Amyloid Load and Cerebral Damage in a Transgenic Mouse Model of Alzheimer's Disease by Treatment with a Beta-Sheet Breaker Peptide. *Faseb J.* 16(8):860-862, 2002.

PODUSLO et al., "Beta-Sheet Breaker Peptide Inhibitor of Alzheimer's Amyloidogenesis with Increased Blood-Brain Barrier Permeability and Resistance to Proteolytic Degradation in Plasma," *Journal of Neurobiology*, 5 June 1999, pp. 371-382, vol. 39, no. 3.

#SIGURDSSON et al. In vivo Reversal of Amyloid-Beta Lesions in the Rat Brain. *J Neuropath Exp Neurol* 59(1): 11-17, 2000

#SOTO et al. Inhibition of Alzheimer's Amyloidosis by Peptides that Prevent Beta-Sheet Conformation. *Biochem Biophys Res Commun.* 226(3): 672-680, 1996

#SOTO et al., "Beta-Sheet Breaker Peptides Inhibit Fibrillogenesis in a Rat Brain Model of Amyloidosis: Implications for Alzheimer's Therapy," *Nature Medicine*, July 1998, pp. 822-826, vol. 4, no. 7.

#SOTO, Claudio, "Alzheimer's and Prion Disease as Disorders of Protein Conformation Implications for the Design of Novel Therapeutic Approaches," *Journal of Molecular Medicine*, May 1999, pp. 412-418, vol. 77 no. 5.

#SOTO, Claudio. Beta-Amyloid Disrupting Drugs. *CNS Drugs* 12(5): 347-356, 1999.

#SOTO, Claudio. Plaque Busters: Strategies to Inhibit Amyloid Formation in Alzheimer's Disease. *Mol Med Today.* 5(8):343-350, 1999.

Serial No.: 10/726,366

#WOOD et al. Prolines and Amyloidogenicity in Fragments of the Alzheimer's Peptide Beta/A4.  
Biochemistry 34:724-730, 1995.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/706,540

Filed: November 4, 2000

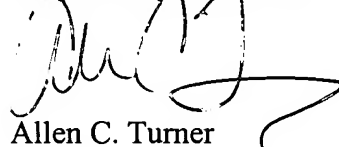
Patent No: 6,689,753

Issue Date: February 20, 2004

For:  $\beta$  SHEET BREAKER PEPTIDE ANALOGS THAT INHIBIT  $\beta$  PLEATED SHEET FORMATION IN AMYLOID  $\beta$  -PEPTIDE, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

This Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,



Allen C. Turner

Registration No. 33,041

Attorney for Applicant(s)

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Telephone: 801-532-1922

Date: December 10, 2004

ACT/alb

Enclosures: Form PTO/SB/08

Cited Documents

Document in ProLaw

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet

1

of

3

**Complete if Known**

Application Number

10/726,366

Filing Date

December 3, 2003

First Named Inventor

Claudio Soto-Jara

**Group Art Unit**

To be assigned

**Examiner Name**

To be assigned

Attorney Docket Number

3154-6317.2US

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]Examiner  
Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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Sheet 2 of 3

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Application Number	10/726,366
Filing Date	December 3, 2003
First Named Inventor	Claudio Soto-Jara
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3154-6317.211S

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#ADESSI et al. Beta-Sheet Breaker Strategy for the Treatment of Alzheimer's Disease. Drug Development Res 56(2): 184-193, 2002.	
		#BLONDELLE et al. Polyalanine-based Peptides as Models for Self-Associated Beta-Pleated-Sheet Complexes. Biochemistry 36: 8393-8400, 1997.	
		European Search Report, EP 00 97 6928, dated September 10, 2004.	
		FAUCHERE et al., "Evaluation of the Stability of Peptides and Pseudopeptides as a Tool in Peptide Drug Design," Advances in Drug Research, 1992, pp. 127-159, vol. 23,	
		GANTE, Joachim, "Peptidomimetics--Tailored Enzyme Inhibitors," Angewandte Chemie, 16 September 1994, pp. 1699-1720, vol. 33, no. 17.	
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		#SIGURDSSON et al. In vivo Reversal of Amyloid-Beta Lesions in the Rat Brain. J Neuropath Exp Neurol 59(1): 11-17, 2000	
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Examiner  
SignatureDate  
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<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 3 of 3

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Filing Date	December 3, 2003
First Named Inventor	Claudio Soto-Jara
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3154-6317 21US

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#SOTO, Claudio, "Alzheimer's and Prion Disease as Disorders of Protein Conformation Implications for the Design of Novel Therapeutic Approaches," Journal of Molecular Medicine, May 1999, pp. 412-418, vol. 77 no. 5.	
		#SOTO, Claudio. Beta-Amyloid Disrupting Drugs. CNS Drugs 12(5): 347-356, 1999.	
		#SOTO, Claudio. Plaque Busters: Strategies to Inhibit Amyloid Formation in Alzheimer's Disease. Mol Med Today. 5(8):343-350, 1999.	
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